IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant:	Dan ALESI et al.	)	
Serial No:	09/920,860	)	
Filed:	August 3, 2001	)	
For:	NEEDLE SAFETY DEVICE WITH TORTUOUS PATH	)	Appeal No.

APPELLANTS' BRIEF ON EX PARTE APPEAL

Commissioner for Patents
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Sir:

This Appeal Brief is submitted in support of the Request to Reinstate the Appeal against the rejection of pending claims 1-3, 5-12, 14-20 and 22-26 of the above-identified application in light of the Office Action dated February 5, 2008 reopening the prosecution of the application.

This is the fourth appeal for this case. A third Appeal Brief was filed on October 1, 2007 to reinstate the Appeal in response to an Office Action dated July 6, 2007 reopening the prosecution of this case. A second Appeal Brief was filed on June 15, 2004 to reinstate the Appeal in response to an Office Action dated March 16, 2004 reopening the prosecution of this case. A first Appeal Brief was filed on September 22, 2003 in response to an After Final Office Action dated May 6, 2003.

By a separate concurrent submission, formal drawings are filed in response to the request by the examiner of such in the February 5, 2008 Office Action.

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REAL PARTY IN INTEREST

The real party in interest for this appeal is Portex, Inc.[1] to whom the inventors assigned the invention per an assignment recorded on August 3, 2001 with the Assignment Branch of the U.S. Patent and Trademark Office.

[1] The name of Portex, Inc. has been changed to Smiths Medical ASD, Inc. since the filing of the 1st Appeal Brief on September 22, 2003.

RELATED APPEALS AND INTERFERENCES

As far as is known and believed, there are no appeals or interferences that would directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1-3, 5-12, 14-20 and 22-26 are pending and stand rejected.

Claims 4, 13 and 21 have been withdrawn.

The claims at issue in this case and herein on appeal accordingly are claims 1-3, 5-12, 14-20 and 22-26, as reproduced in the Claims Appendix. For the convenience of the Board, withdrawn claims 4, 13 and 21 are included and noted as such in the Claims Appendix.

STATUS OF AMENDMENTS

No Amendment has been filed subsequent to the Office Action dated February 5, 2008 reopening the prosecution of this case.

Nor has there any amendment filed in response to the Office Actions dated July 6, 2007 and March 16, 2004 reopening the prosecution of this case, or the final rejection Office Action dated May 6, 2003.

SUMMARY OF CLAIMED SUBJECT MATTER

INDEPENDENT CLAIMS

Claim 1

The instant invention, as set forth in claim 1, relates to an apparatus that comprises a holder (2) having one and other ends (4, 6), with the one end having an extension (8) and a sleeve (14) extending from the extension [Page 6, lines 15-16; Fig. 3].[2] A double ended needle (18) having a base (24) is mated to the extension (8) of the holder . One end of the needle (20) extends away from the holder while the other end of the needle extends into the holder. The base (24) of the needle is substantially positioned within the sleeve (14) [Page 6, lines 6-9; Figs. 5, 6, 8]. A collar (10) having a housing (12) pivotally extending therefrom is mounted about the extension (8) [Page 9, lines 3-7; Figs. 2, 5-8]. A sheath (28) that has an open end is matingly fitted to the sleeve (14) to establish an environment sealed against bacteria intrusion for the one end of the needle (20) [Page 7, lines 10-20; Fig. 6].

The instant invention therefore is directed to establishing for an apparatus a sealed environment for maintaining the sterility of the needle to be used on a patient, by providing a sheath that mates to a sleeve, which extends from an extension, or the neck, of the holder to which the needle is mated. By providing a sleeve that extends from the extension, or neck, of the holder, no modification is required for the holder, which may be a conventional Vacutainer holder, as the collar of the needle protection housing (that shields the needle after use) continues to be mounted to the extension of the holder.[3] Thus, the claim 1 invention establishes an environment sealed against bacteria intrusion for the

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[2] The designations of the different elements recited in the claims are in parenthetical while the pages of the disclosure that provide support are bracketed.

[3] The holder may also be modified in the embodiment as set forth in claim 3 where the sleeve integrally extends from the extension.

needle prior to use without any need to modify either the holder or the double-ended needle.

Claim 10

Independent claim 10 relates to a blood drawing device having a holder (2) which, due to the interaction of the sheath (28) fitted to the sleeve (14) that extends from the neck (8) of the holder (2), as well as the mating of the double-ended needle by means of its base (24) into the neck (8) of the holder, establishes an environment impervious to bacteria intrusion for the space (34) inside the sheath that encloses the needle (20) that is to be used with a patient. A collar (10) having a housing (12) pivotally connected thereto is mounted about the neck (8) of the holder (2). [Page 6, lines 6-9; Page 9, lines 3-7; Page 7, lines 10-20; Figs. 2, 5-8] The blood drawing device embodiment of claim 10 has the same advantages discussed above with respect to claim 1.

Claim 18

Independent claim 18 relates to a needle device that comprises a body (2) having a neck (8) to which a needle (20) is connected via a base (24). There is also a sleeve (14) that extends from the neck (8) to enclose the base (24). A collar (10) having a housing (12) connected thereto is mounted about the neck (8). By means of the combination of the open end of a sheath (28) that matingly fits to the sleeve (14) to cover needle (20), the base (24) that is mated to the neck (8) of the body (2) and the sleeve (14) that extends from the neck, an environment impervious to bacteria intrusion inside the space of the sheath (28) where the needle (20) resides is established. [Page 6, lines 6-9; Page 9, lines 3-7; Page 7, lines 10-20; Figs. 2, 5-8]

DEPENDENT CLAIMS

Claims 2, 11, 19

Other aspects of the invention include the recitation of the interaction between the different surfaces (28s, 14s) of the sheath (28) and sleeve (14) that together effect a tortuous path (30) to seal the inside of the sheath against potential bacteria intrusion [Page 7, lines 12-20; Fig. 6]. This aspect of the invention is set forth in dependent claim 2 and in more detail in dependent claims 11 and 19.

Claims 3, 12, 20

Claims 3, 12 and 20 each define sleeve (14) to be integrally extending from the extension or the neck (8) of the holder [Page 6, lines 15-16; Figs. 2 and 4-6].

Claims 5, 14, 22

Claims 5, 14 and 22 each define housing (12) to have an integral locking means (46) for grasping the needle (20) when the housing is pivoted to cover the needle after the sheath (28) has been removed from the sleeve [Page 9, lines 3-8; Fig. 5].

Claims 6, 15, 23

The coacting locking portions provided at the collar (10) or sleeve (14), and the housing (12) are defined in claims 6, 15 and 23.

Claims 7, 16, 26

Claims 7, 16 and 26 each define the placing of a cover (16) at the end (6) of the holder (2) to provide a sterile environment for the interior space (19) of the holder [Page 6, lines 17-21; Figs. 4, 5].

Claims 9, 16, 24

Claims 9, 16 and 24 define either means or a tamper seal (40) provided on the sheath (28) and the sleeve (14) to evidence the sealed environment (34) for the needle (20) [Page 8, lines 13-17; Fig. 2].

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

In the Office Action dated February 5, 2008 reopening prosecution of this case, the examiner has rejected claims 1-3, 5-8, 10-12, 14-15, 17-20, 22-23 and 25-26 under 35 U.S.C. 102(e) as being anticipated by Newby et al. (US 6,298,541). Claim 7 was rejected under 35 U.S.C. 103(a) as being obvious over the combination of Newby and Thorne (US 5,823,991). Claims 9 and 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Newby and Imbert (US 6,027,482). Claim 16 was rejected under 35 U.S.C. 103(a) as being unpatentable over Newby in view of Thorne and Imbert.

In view of the examiner's rejections, the grounds presented herein on appeal are the following:

1. Whether claims 1-3, 5-8, 10-12, 14-15, 17-20, 22-23 and 25-26 are patentable in view of Newby under 35 U.S.C. 102(e)?

2. Whether claim 7 is patentable in view of Newby and Thorne under 35 U.S.C. 103(a)?

3. Are claims 9 and 24 unpatentable in view of the combination of Newby and Imbert under 35 U.S.C. 103(a)?

4. Is claim 16 unpatentable in view of Newby in combination with Thorne and Imbert under 35 U.S.C. 103(a)?

ARGUMENT

Issue 1

Each of claims 1-3, 5-8, 10-12, 14-15, 17-20, 22-23 and 25-26 stands rejected under 35 U.S.C. 102(e) as being anticipated by Newby et al. (US 6,298,541).

"In order to prove that a claim is anticipated under 35 U.S.C. 102(b), defendants must present clear and convincing evidence that a single prior art reference discloses, either expressly or inherently, each limitation of the claim." *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1348 (Fed. Cir. 2002). In *In re Robertson*, the CAFC further held: "Anticipation under 35 U.S.C. 102(e) requires that `each and every element as set forth in the claim is found either expressly or inherently described, in a single prior art reference`". 169 F.3d 743, 746 (Fed. Cir. 1999)

Independent Claims 1, 10, 18

Claim 1 recites a holder that has an extension at its one end, and a sleeve extending from the extension. A collar is mounted about the extension. Moreover, the apparatus of claim 1 includes a double ended needle having a base mated to the extension at the one end of the holder, with the base being substantially positioned within the sleeve. One end of the needle extends away from the holder. Furthermore, the apparatus of claim 1 includes a sheath that matingly fits to the sleeve to establish an environment which seals the needle of the double ended needle that extends away from the holder from bacteria intrusion.

Claim 10 defines a blood drawing device that has a holder which has one end having a neck to which a sleeve extends. A collar having a housing is mounted about the neck. The base of a double ended needle is connected to the neck of the holder with one

end of the needle extending away from the holder. The base is positioned substantially within the sleeve. A sheath is fitted to the sleeve in such a way that the sleeve, the base and the sheath in combination establish an environment for the space inside the sheath that encloses the needle impervious to bacteria intrusion.

Claim 18 defines a needle device that has a body having a neck to which a needle is connected by means of a base. A collar having a housing is mounted about the neck. The needle device of claim 18 has a sleeve that extends from the neck to enclose the base, and a sheath that fits to the sleeve such that the sleeve, the base and the open end of the sheath that mates to the sleeve in combination establish a bacteria free space inside the sheath where the needle extends from the base.

Newby et al. (US 6,298,541 hereafter Newby) discloses a needle assembly that is best shown in its assembled form in Fig. 1. With reference to the dissembled view of Fig. 2, the Newby device includes a double ended needle having a needle hub 60 that fits into a collar 90. A housing shield 140 is attached to collar 90 by way of its hanger bar 182 snap-fitted to hook 114 at collar 90. A rigid sleeve shield 50 is fitted into the forward annular skirt 92 of collar 90, by way of the former's proximal portion mating with the inner wall 96 of collar 90. A second rigid sleeve shield 52 is fitted to the rear annular skirt 94 of collar 90. When assembled, the Newby device is as shown in Fig. 1. Thus, at best, the only time that the Newby device is sterile is when it is shipped per assembled as shown in Fig. 1.

The assembly of the different components of the Newby device as shown in Fig. 2 is best explained in column 6, lines 16-28. There, it is disclosed that needle 60 is joined to collar 90 by ultrasonic welding techniques or any other bonding techniques or

mechanical fit, so that collar 90 is aligned with the intravenous end (or beveled end) of needle 44. This is so that shield 140 could be connected to collar 90 in such a way that it would not block the view of a user, who has to look at the beveled end of needle 44, in order to accurately insert the needle into the vein of the patient. Thus, in contrast to the assertion by the examiner, collar 90 of the Newby device is not a rotatable collar and does not mounted about the neck of a Vacutainer holder.

The Newby device does not include a holder and a sleeve extending from the neck or extension of the holder, for when the Newby device is connected to a Vacutainer holder, such as that shown in Figs. 7-8, and even assuming that the holder is part of the Newby device, there remains the fact that there is no sleeve present in such a device.

Each of claims 1, 10 and 18 requires that the open end of the sheath be matingly fitted to the sleeve. For the Newby device, assuming that it has been threaded into a Vacutainer holder as shown in Fig. 8, only the rigid sleeve sheath 50 remains fitted to collar 90. In other words, the second rigid sleeve sheath 52 has to be first removed from the Newby device as shown in Figs. 1 and 2 before the device could be threaded into a Vacutainer holder, per shown in Figs. 8-10. The Newby device shown in Figs. 8-10 therefore is no longer completely sterile. It is unfortunate that Newby refers to his shield 50 as a rigid sleeve. But the disclosure of Newby clearly disclose that shield 50 is fitted into collar 90 to cover needle 44 before use, and accordingly shield 50 is not and could not be equated with the sleeve (14) shown and claimed in the instant invention.

The examiner also appears to refer to component 92 as the sleeve in the Newby device (page 3 of the Office Action where the examiner states "a sleeve (extending portion from topmost portion)"). Yet component 92 is nothing more than the forward annular skirt

of collar 90, and in fact is part of the collar where its inner wall 96 is fitted into by the proximal portion of shield 50. Further, if the forward annular skirt 92 were to be construed as the claimed sleeve, then Newby clearly fails to disclose any collar mounted about the neck of the holder. In fact, no such collar exists in the Newby device, even in view of the device shown in Figs. 1-2 having been mated to a Vacutainer holder per shown in Figs. 8-12. Thus, the devices set forth in independent claims 1, 10 and 18 are not the same as the device shown in Fig. 13 of Newby, per asserted by the examiner.

The examiner moreover posits that "the open end of the sheath is sealed and effects a tortuous path with the sleeves to prevent contamination of bacteria or other intrusion (columns 1-3)." At pages 3-4 of the Office Action. There is nothing in columns 1-3 of Newby that discloses or even remotely suggests that the fitting of the shield 50 to the forward end of collar 90 of the Newby device, which is conventional, has anything to do with establishing a tortuous path or establishing an environment that is impervious to bacteria intrusion in the space inside sheath 50.

In sum, Newby fails to disclose the claimed invention of independent claims 1, 10 and 18, insofar as Newby does not disclose any sleeve that extends from the neck of a holder, or a collar having a housing for covering needle that is mounted about the neck of the holder, or a sheath that in combination with its mated sleeve form an environment that is impervious to bacteria intrusion. Accordingly, appellant respectfully submits that independent claims 1, 10 and 18 each are not anticipated by Newby.

Claims 7, 16, 26

Newby fails to disclose any cover that seals the open end of the vacuum tube holder to provide a sterile environment for the space (19) within the vacuum tube holder as

defined in claims 7, 16 and 26. At best, Newby shows a vacuum tube holder, with an open end, for accepting the Newby device as shown in Figs. 1 and 2.

The examiner has not provided any evidence in Newby to support this rejection. If anything, while essentially copying the same Section 102(e) rejection paragraph from the Office Action of July 6, 2007 to support his Section 102(e) rejection for the latest Office Action, the examiner in fact has removed the last sentence of that paragraph which he had used to support his earlier rejection of claims 7, 16 and 26.[4]

Claims 17, 25

Newby fails to disclose that collar 90 be rotatable about the extension, as required in claim 8, or be rotatable about the neck, per required by claims 17 and 25. As was discussed earlier, the needle hub 60 is fixed to the inside of collar 90 for the Newby device.

Claims 11, 19

Appellants respectfully submit that Newby fails to disclose the requirement for the establishment of a tortuous path in claims 11 and 19. Each of those claims requires the surfaces of the sheath to come into contact with the respective surfaces of the base and the sleeve. There is nothing in Newby that discloses that the proximal portion of sheath 50 comes into contact with needle hub 60. If anything, the cross-sectional view of collar 90 illustrated in Fig. 10 of Newby shows that the needle hub 60 is well within the recess annular skirt 94, so that only needle 44 is extending from the forward annular skirt 92 of collar 90. In other words, the proximal portion of sheath 50 could not possibly come into contact with needle hub 60 for the Newby device.

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[4] The only differences that applicants can see between the two Office Actions for the Section 102(e) rejection is that the current rejection added explanation for the "sleeve" in parenthetical and deleted the last sentence of the Section 102(e) rejection in the July 6, 2007 Office Action.

Claims 3, 12 and 20

Each of claims 3, 12 and 20 defines the sleeve to be integrally extending from the extension or the neck of the holder.[5] In other words, the instant invention calls for a sleeve extending from an extension of a holder, with claims 3, 12 and 20 each requiring that the sleeve be integrally extending from the holder extension.

In contrast, the only thing shown in Fig. 13 of Newby is the hub of a double ended needle mated to a Vacutainer holder. Claims 3, 12 and 20 depend from independent claims 1, 10 and 18, respectively, and each of those independent claims requires that the base of the double ended needle be positioned within the sleeve (or the sleeve enclosing the base in claim 18). Newby fails to meet such limitations of claims 3, 12 and 20, for Fig. 13 shows that the lower part of the double ended needle hub is attached to the Vacutainer luer end instead of being positioned within a sleeve. Indeed, Fig. 13 of Newby does not show a sleeve integrally extending from the neck of a holder. And even given the examiner's position that the forward annular skirt 92 of collar 90 is a sleeve, it remains that collar 90 is not part of the neck of the holder, per clearly shown in Fig. 10 of Newby. Putting it simply, under the examiner's assumption, collar 90 would extend from the neck of the Vacutainer holder. Yet such is not the case, for Fig. 10 particularly shows that collar 90 is a separate component from the Vacutainer holder. This is supported by the different cross hatchings of those components.

In sum, Appellant respectfully submit that each of independent claims 1, 10 and 18 is not anticipated by Newby. Moreover, Appellants respectfully submit that at least

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[5] The examiner has not shed any light on this new anticipation rejection of claims 3, 12 and 20, for the Section 102(e) rejection that the examiner set forth in the February 5, 2008 is in essence a repeat of the Section 102(e) rejection in the previous Office Action dated July 6, 2007. See footnote 4 above.

dependent claims 3, 7, 8, 11, 12, 17, 19, 20, 25 and 26, per discussed above, each are separately patentable over Newby.

Issue 2

Claim 7 stands rejected under 35 U.S.C. 103(a) as being obvious over Newby in view of Thorne.

As claim 7 depends from claim 1, it is applicants' position that claim 7 stands or falls with the anticipation rejection of claim 1 under Newby.

Issue 3

Claims 9 and 24 stand rejected under 35 U.S.C. 103(a) in view of the combination of Newby and Imbert (US 6,027,482).

Claims 9 and 24 depend from independent claims 1 and 18, respectively, and those claims recite means [claim 9] or a tamper seal [claim 24] on the sheath and the sleeve to provide evidence that the sealed environment of the needle has been compromised. Insofar as neither Newby nor Imbert discloses any sleeve, that alone renders claims 9 and 24 not obvious over the combination of Newby and Imbert.

Issue 4

Claim 16 stands rejected under 35 U.S.C. 103(a) in view of Newby in combination with Thorne and Imbert.

Claim 16 depends from claim 10. It is applicants' position that claim 16 stands or falls with the anticipation rejection of claim 10 under Newby, for if there is no sleeve taught in Newby, there cannot be a tamper seal on a non-sleeve.

In summation, Appellants respectfully submit that the prior art rejections of the at issue claims, as discussed above, each are not sustainable. Accordingly, Appellants respectfully request that the examiner's rejections of pending claims 1-3, 5-12, 14-20 and 22-26 be reversed.

Respectfully submitted,

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Date: May 5, 2008

CLAIM APPENDIX

1. (original) Apparatus, comprising:

a holder having one and other ends, said one end having an extension and a sleeve extending from said extension;

a double ended needle having a base mated to said extension of said one end of said holder, one end of said needle extends away from said holder while other end of said needle extends into said holder, said base of said needle being substantially positioned within said sleeve;

a collar mounted about said extension;

a housing pivotally extending from said collar;

a sheath having an open end, said open end having a circumference that enables the sheath to matingly fit to said sleeve to establish an environment sealed against bacteria intrusion for said one end of said needle.

2. (original) Apparatus of claim 1, wherein the surface of the open end of said sheath and the surface of said sleeve that come into contact with each other effect a tortuous path to seal the inside of said sheath against potential bacteria intrusion.

3. (original) Apparatus of claim 1, wherein said sleeve integrally extends from said extension.

4. (withdrawn) Apparatus of claim 1, wherein said sleeve comprises a semi-closed end having an opening substantially matching the opening of said extension and through which the portion of said base of said needle that mates to said extension passes, said sleeve sealingly fitting onto said extension when said base of said needle is mated to said extension.

5. (original) Apparatus of claim 1, wherein said housing further comprises an integral locking means for grasping said one end of said needle when said housing is pivoted to cover said one end of said needle after said sheath has been removed from said sleeve.

6. (previously presented) Apparatus of claim 1, wherein said housing comprises at least one locking portion that coacts with at least another locking portion at said collar or said sleeve to fixedly retain said housing along a longitudinal axis of said holder to cover said one end of said needle after said sheath has been removed from said sleeve.

7. (original) Apparatus of claim 1, further comprising:

a cover sealing said other end of said holder to provide a sterile environment for the inside of said holder.

8. (original) Apparatus of claim 1, wherein said collar is rotatable about said extension so that said housing is rotatable relative to said one end of said needle.

9. (original) Apparatus of claim 1, further comprising:

means on said sheath and said sleeve to provide evidence that the sealed environment of said one end of said needle has been compromised.

10. (original) Blood drawing device comprising a holder having one and other ends, said one end having a neck to which a sleeve extends, a double ended needle connected to said neck via a base so that one end of said needle extends away from said holder and other end of said needle extends within said holder, a collar having a housing pivotally connected thereto mounted about said neck, a sheath having an open end matingly fitted to said sleeve, wherein said base is positioned substantially within said sleeve and said open end of said sheath is fitted to said sleeve in such a way that said sleeve, said base and said open end of said sheath in combination establish an environment impervious to bacteria intrusion for the space inside said sheath that encloses said one end of said needle.

11. (original) Device of claim 10, wherein the surfaces of said sheath that come into contact with the respective surfaces of said base and said sleeve effect a tortuous path to seal said space inside said sheath that encloses said one end of said needle.

12. (original) Device of claim 10, wherein said sleeve integrally extends from said neck.

13. (withdrawn) Device of claim 10, wherein said sleeve comprises a semi-closed end having an opening substantially matching the opening of said neck sealingly fitted onto said neck when said needle is connected to said neck.

14. (original) Device of claim 10, wherein said housing further comprises an integral locking means for grasping said needle when said housing is pivoted to cover said needle after said sheath has been removed from said sleeve.

15. (original) Device of claim 10, wherein said housing comprises at least one locking portion that coacts with at least an other locking portion at said collar or said sleeve to fixedly retain said housing along a longitudinal axis of said holder to cover said needle after said sheath has been removed from said sleeve.

16. (original) Device of claim 10, further comprising:

a cover sealing said other end of said holder to provide a sterile environment for the inside of said holder; and

a tamper seal on said sheath and sleeve that, when broken, provides evidence that the sealed environment of said needle has been compromised.

17. (original) Device of claim 10, wherein said collar is rotatable about said neck and said housing is rotatable relative to said needle.

18. (original) A needle device comprising a body having a neck to which a needle is connected via a base, a sleeve extending from said neck to enclose said base, a collar having a housing for covering said needle pivotally connected thereto mounted about said neck, a sheath having an open end matingly fitted to said sleeve, said sleeve, said base and said open end of said sheath that mates to said sleeve in combination establish an environment impervious to bacteria intrusion for the space inside said sheath that encloses said needle.

19. (original) Device of claim 18, wherein the surfaces of said sheath that come into contact with the respective surfaces of said base and said sleeve effect a tortuous path to seal said space inside said sheath that encloses said one end of said needle.

20. (original) Device of claim 18, wherein said sleeve integrally extends from said neck.

21. (withdrawn) Device of claim 18, wherein said sleeve comprises a semi-closed end having an opening substantially matching the opening of said neck sealingly fitted onto said neck when said needle is connected to said neck.

22. (original) Device of claim 18, wherein said housing further comprises an integral locking means for grasping said needle when said housing is pivoted to cover said needle after said sheath has been removed from said sleeve.

23. (original) Device of claim 18, wherein said housing comprises at least one locking portion that coacts with at least an other locking portion at said collar or said sleeve to fixedly retain said housing along a longitudinal axis of said holder to cover said needle after said sheath has been removed from said sleeve.

24. (original) Device of claim 18, further comprising:

a tamper seal on said sheath and sleeve that, when broken, provides evidence that the sealed environment of said needle has been compromised.

25. (original) Device of claim 18, wherein said collar is rotatable about said neck and said housing is rotatable relative to said needle.

26. (original) Device of claim 18, wherein said body comprises a Vacutainer holder having one end wherefrom said neck extends and an other open end sealed with a cover to provide a sterile environment within said holder.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.